IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

SUSAN NEVOLAS,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. CIV-15-894-M
	)	
BOSTON SCIENTIFIC CORPORATION,	)	
	)	
Defendant.	)	

ORDER

Before the Court is defendant's Motion to Dismiss Plaintiff's Second Amended Complaint, filed February 29, 2016. On March 21, 2016, plaintiff filed her response, and on March 28, 2016, defendant filed its reply.

I. Introduction

Plaintiff has brought the instant action to recover damages for injuries she allegedly sustained after she was implanted in September 2012 with a spinal stimulator, a/k/a The Precision Spinal Cord Stimulator System (the "Precision System"), consisting of an Implantable Pulse Generator ("IPG"), model SC-1010C, manufactured by defendant Boston Scientific Corporation. The Precision System is a Class III Medical Device. Plaintiff alleges that the Precision System suffers from one or more of the following manufacturing defects: (1) the devise battery was defective causing it to overheat; (2) the device overheating could not be fixed by reprogramming; and (3) the polymer separator inside the battery failed to permanently disable the battery once the battery began to overheat. *See* Plaintiff's Second Amended Complaint [docket no. 39] at ¶ 25. Plaintiff further alleges that because of the defects, she was required to undergo an additional surgery to remove the original device. Defendant now moves the Court to dismiss plaintiff's Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

II. Standard for Dismissal

Regarding the standard for determining whether to dismiss a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), the United States Supreme Court has held:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotations and citations omitted). Further, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not shown - that the pleader is entitled to relief." *Id.* at 679 (internal quotations and citations omitted). Additionally, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Id*. at 678 (internal quotations and citations omitted). A court "must determine whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed." *Lane v. Simon*, 495 F.3d 1182, 1186 (10th Cir. 2007) (internal quotations and citation omitted). Finally, "[a] court reviewing the sufficiency of a complaint presumes all of plaintiff's factual allegations are true and construes them in the light most favorable to the plaintiff." *Hall v. Bellmon*, 935 F.2d 1106, 1109 (10th Cir. 1991).

III. Discussion

Defendant asserts that plaintiff's Amended Complaint should be dismissed for the following two independent reasons: (1) because federal law expressly or impliedly preempts plaintiff's claims related to the Precision System, and (2) because plaintiff fails to plead sufficient facts under Federal Rule of Civil Procedure 8 to plausibly support her negligence-based claims. Plaintiff contends that her claims are not preempted by federal law and meet the pleading standard required by Rule 8.

It is undisputed that the Precision System is subject to the United States Food and Drug Administration's ("FDA") intensive Premarket Approval ("PMA") process and that the FDA approved the Precision System. By passing the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360, the United States Congress ceded exclusive regulatory authority over medical devices to the FDA because it determined that satisfaction of the FDA's PMA requirements are adequate, as a matter of law, to safeguard the American public in its use of medical devices. The MDA includes an express preemption provision that states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[1] In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court employed a two-step analysis for determining whether state law claims are preempted under § 360k(a). First, the Supreme Court considered whether PMA of a medical device by the FDA

[1]The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption.

imposes federal "requirements" under the MDA. *See Riegel*, 552 U.S. at 321-23. The Court concluded that PMA imposes federal "requirements" within the meaning of the MDA. *See id.* at 322-23. Second, the Supreme Court considered whether the state common law claims would impose requirements "different from, or in addition to" the requirements imposed by the PMA process and that relate to safety and effectiveness. *See id.* at 322-23. The Court concluded that the plaintiffs' state common law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device would impose requirements "different from, or in addition to" the requirements imposed by the PMA process. *Id.* at 323. When determining whether a state requirement is "in addition to" the requirements imposed by federal law, courts have found "[w]here a federal requirement permits a course of conduct and the state makes its obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (internal quotations and citation omitted).

However, the Supreme Court has made clear that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330.

> In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.

Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1300 (8th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original). Further, "[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Id.* at 1301 (internal quotations and citation omitted). "Plaintiffs must also allege a link between the failure to comply and the alleged injury." *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 204 (W.D.N.Y. 2011).

In her response, plaintiff asserts that she has sufficiently pled parallel claims to survive federal law preemption. Specifically, plaintiff alleges that her Second Amended Complaint alleges the state common law and federal regulations she contends defendant violated and identifies the precise failures of defendant to comply with the FDA-approved PMA specifications, and that at this point in litigation, it is impossible for her to plead with further specificity given the limited amount of information that is publicly available.

Having carefully reviewed plaintiff's Second Amended Complaint, the Court finds that while plaintiff has set forth some additional allegations in her Second Amended Complaint regarding approved design standards for the Precision System, plaintiff has still failed to sufficiently state any parallel claims to survive federal law preemption. Specifically, the Court finds that in plaintiff's Second Amended Complaint, the allegations, including the new allegations included in the Second Amended Complaint, are still merely conclusory and are devoid of any real factual support. Plaintiff in essence alleges, in a conclusory manner, that defendant violated the conditions of the FDA's approval and the general regulations applicable to Class III medical devices. For example, plaintiff alleges:

> 25. The Precision System Mr. Nevolas received was not manufactured in strict compliance with the Approved Design

Standards set forth above. The Approved Design Standards describe the only acceptable end result of the manufacturing process for the Precision System, and the Precision System Ms. Nevolas received does not match that end result. Accordingly, the device Ms. Nevolas received violates the conditions of the FDA's approval and the general regulations applicable to Class III medical devices. Specifically, Ms. Nevolas' Precision System suffers from one or more of the following manufacturing defects:

a. The device battery was defective causing it to overheat;

b. The device overheating could not be fixed by reprogramming; and

c. The polymer separator inside the battery failed to permanently disable the battery once the battery began to overheat.

* * *

27. Defendant violated the conditions of the FDA's approval by failing to adhere to the Good Manufacturing Practices ("GMPs") promulgated by the FDA which are mandatory requirements for all Class III medical devices.

28. Defendant violated 21 C.F.R. § 820.30 by failing to establish and maintain procedures to control the design of the Precision System. As a result, the Precision System Ms. Nevolas received did not comply with the Approved Design Standards as set forth above, causing the injuries set forth herein.

29. Defendant violated 21 C.F.R. § 820.70 by failing to adhere to federally mandated production and process controls. Had Defendants adhered to the requirements of § 820.70, the Precision System Ms. Nevolas received would have complied with the Approved Design Standards, and Ms. Nevolas would not have suffered the injuries set forth herein.

30. Defendant violated 21 C.F.R. § 820.86 by failing to identify acceptance criteria for the conformance or nonconformance of the Precision System throughout the manufacturing, packaging, labeling, installation, and servicing of the product. As a result, The Precision System that Ms. Nevolas received was not identified as non-conforming and was allowed to be distributed and sold despite its failure to adhere to the Approved Design Standards. Ms. Nevolas suffered the injuries described herein due to this failure to identify acceptance criteria for Ms. Nevolas' Precision System.

31. Defendant violated 21 C.F.R. § 820.90 by failing to establish and maintain procedures to identify, document, evaluate, segregate,

> and dispose of products like the Precision System that Ms. Nevolas received that do not conform to the Approved Design Standards. If Defendants had complied with § 820.90, the device Ms. Nevolas received would have been identified as nonconforming and would have been offered for sale. As a result of Defendant's failure, Ms. Nevolas received a nonconforming Precision System and was injured as set forth herein.
>
> 32. Defendant violated the Manufacturer Reports Requirements contained in 21 C.F.R. §§ 803.50, 803.52, 803.56, and 803.58 by failing to report adverse injuries similar to those suffered by Ms. Nevolas. Had Defendant reported these adverse events as required by law, Ms. Nevolas and her doctors would have been able to make an informed decision regarding the Precision System. Instead, Ms. Nevolas was allowed to receive a device that did not comply with the Approved Design Standards, causing Ms. Nevolas' injuries as set forth herein.

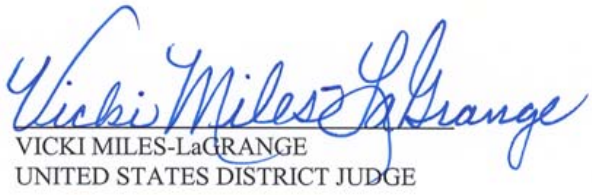
Second Amended Complaint at ¶¶ 25, 27-32.

The Court recognizes that individuals in plaintiff's position are handicapped because "[i]n the case of Class III medical devices, potentially valuable information related to PMA is kept confidential as a matter of federal law and formal discovery may be required before a plaintiff can fairly be expected to identify specific defects." *Comella v. Smith & Nephew, Inc.*, No. 13 C 1850, 2013 WL 6504427, at *3 (N.D. Ill. Dec. 11, 2013) (internal citation omitted). "However, more is required to make out a parallel claim than conclusory statements that a defendant violated multiple regulations." *Swisher v. Stryker Corp.*, No. CIV-14-0028-HE, 2014 WL 1153716, at *2 (W.D. Okla. Mar. 14, 2014). The Court finds plaintiff's conclusory allegations that defendant violated the conditions of the FDA's approval and the general regulations applicable to Class III medical devices are insufficient to state a plausible parallel claim upon which relief can be granted.

IV. Conclusion

Accordingly, for the reasons set forth above, the Court GRANTS defendant's Motion to Dismiss Plaintiff's Second Amended Complaint [docket no. 40] and DISMISSES plaintiff's Second Amended Complaint.

IT IS SO ORDERED this 15th day of April, 2016.



VICKI MILES-LaGRANGE
UNITED STATES DISTRICT JUDGE